PATENT

IN THE U.S. PATENT AND TRADEMARK OFFICE

Appellants:	Klaus ABRAHAM-FUCHS, et al.
Application No.:	10/589,536
Art Unit:	3686
Conf. No.:	8473
Filed:	August 16, 2006
Examiner:	Edward B. Winston, III
For:	METHOD FOR EVALUATING THE QUALITY OF ELECTRONICALLY STORED, PARTICULARLY MEDICAL, KNOWLEDGE DATA
Atty. Dkt. No.:	32860-001075/US

February 10, 2011

Customer Service Window
Randolph Building
401 Dulany Street
Alexandria, VA 22313
Mail Stop **APPEAL BRIEF – PATENT**

APPELLANT'S BRIEF ON APPEAL UNDER 37 C.F.R. §41.37

In accordance with the provisions of 37 C.F.R. § 41.37, Appellants submit the following Appeal Brief.

02/11/2011 SMOHAMME 00000001 10589536
01 FC:1402 540.00 OP

I. 37 C.F.R. § 41.37(c)(1)(i) – REAL PARTY IN INTEREST

The real party in interest is Siemens Aktiengesellschaft. An assignment of the rights associated with the present application was recorded with the United States Patent and Trademark Office on August 16, 2006 on reel/frame no. 018198/0398.

II. 37 C.F.R. § 41.37(c)(1)(ii) – RELATED APPEALS AND INTERFERENCES

There are no known appeals, interferences, or judicial proceedings that will directly affect, be directly affected by, or have a bearing on the Board's decision in this Appeal.

III. 37 C.F.R. § 41.37(c)(1)(iii) – STATUS OF CLAIMS

Claims 1-19 and 22-30 are pending in this application, with claims 1 and 29 being in independent form. Each of claims 1-19 and 22-30 remain finally rejected and are being appealed.

1. Claims 1-19 and 22-30 stand rejected under 35 U.S.C. §102(e) as being unpatentable over U.S. Patent Application Publication No. 2004/0122719 ("Sabol").

Claims 1-19 and 22-30 are being appealed.

IV. 37 C.F.R. § 41.37(c)(1)(iv) – STATUS OF AMENDMENTS

No amendments were filed subsequent to the June 24, 2010 Final Office Action.

V. 37 C.F.R. § 41.37(c)(1)(v) – SUMMARY OF CLAIMED SUBJECT MATTER

Introduction

The following explains the subject matter set forth in each claim argued on appeal and each independent claim by way of example embodiments in the specification by page and line number, and in the drawings, if any, by reference characters only to satisfy 37 C.F.R. § 41.37(c)(1)(v). This concise explanation relies on example embodiments from the specification to describe the claims; however, the claims recite subject matter not limited to these example embodiments.

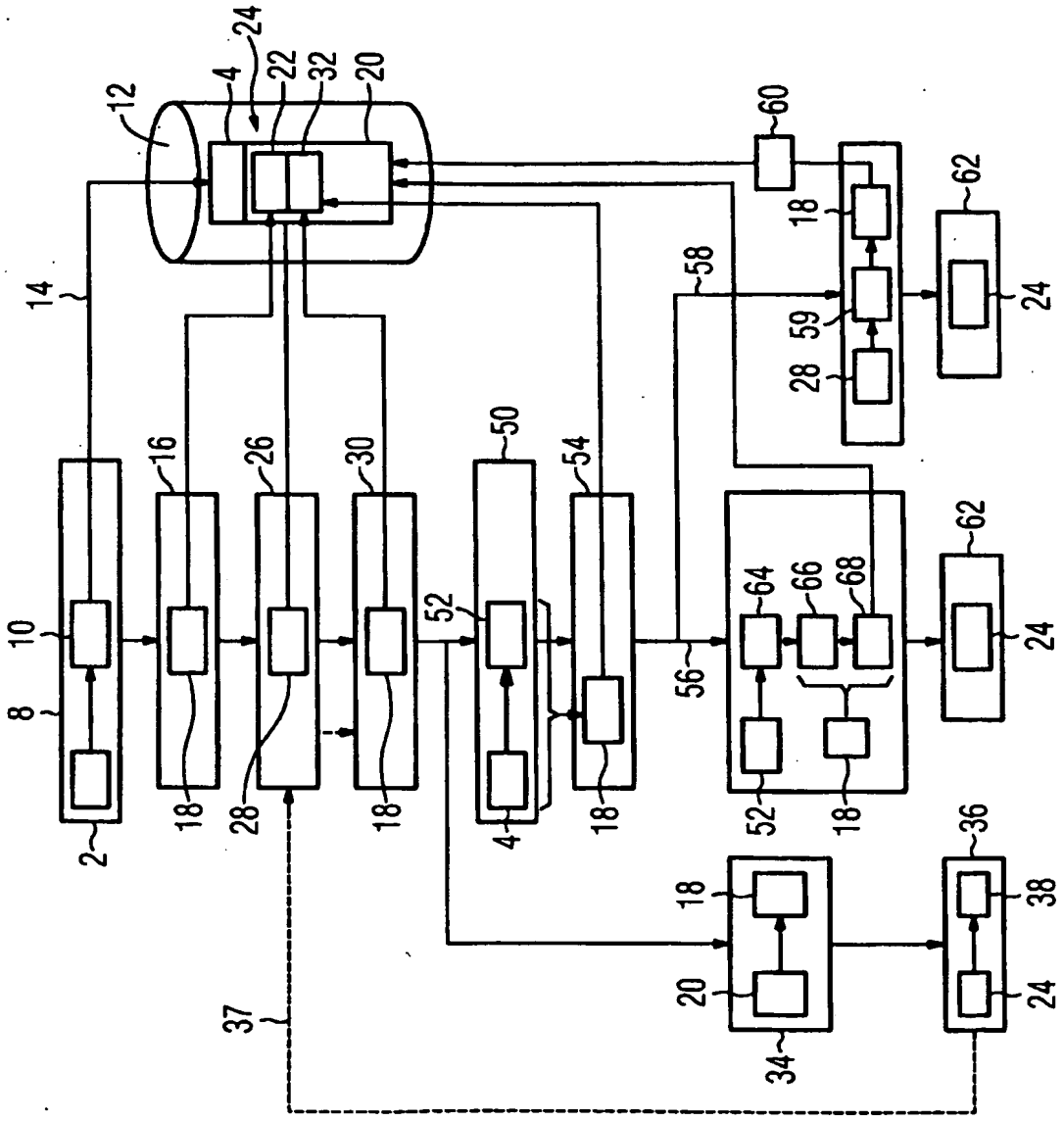
Fig. 1 shows a flow chart for the quality evaluation of the description of a cancer therapy, according to a non-limiting embodiment of the present invention. FIG. 1 is reproduced below.

According to example embodiments, a research institution 2 may develop a new method for cancer therapy and compile an accurate description 4 of it. The new method, for example, is supposed to reduce the therapy time until a cancer lesion vanishes from previously 12 to 8 months.

According to example embodiments, in a starting step 8 of the quality evaluation method represented in Fig. 1, as indicated by the arrow 14, the research institution 2 sends the description 4 and all relevant information, working procedures etc. of the method to an internet service provider 10, which stores the description 4 in a data memory 12 connected to the Internet.

According to example embodiments, in a first quality assurance step 16, a quality management system 18 present at the internet service provider 10 adds quality data 20 to the description 4 stored in the data memory 12. An abstract 22 is stored in the quality data. The abstract contains the originator of the knowledge, for example, the research institution 2, date, person and description data of the

development of the method and the persons, contacts involved in it. Access data 32, which contain information about the write and read access to the description 4, are furthermore added to the quality data 20. The quality data 20 correlated with the description 4 may thus represent metadata for the description 4.



According to example embodiments, the quality data 20 and the associated description 4 are inseparably connected together, for example by a capsule technology. This creates a knowledge capsule 24 which, besides the actual knowledge i.e. the description 4, contains the quality data 20 associated with the

knowledge. Each access to the knowledge data in the form of the description 4, for example, reading, writing, forward communication, evaluation, requires "opening" of the capsule, which can in turn be documented, tracked or protected by password access or the like.

According to example embodiments, in a reading step 26, a doctor 28 planning a cancer therapy on a patient 52 learns about the new cancer therapy method through the description 4 by reading the knowledge capsule 24 out from the data memory 12. Since the description 24 can only be opened, for example, read out, inside and together with the entire capsule 24, the doctor also automatically obtains all the metadata about the description 4 and the currently available quality data 20.

According to example embodiments, the abstract 22 tells the doctor 28 that the description 4 was developed by the research institution 2, with which they have had extremely good experience in the past. They know the scientists involved in the development personally and trust them. From the access data 32, they find that the description 4 has never yet been read, for example, there is not yet any further experience about it. The doctor 28 decides to carry out the method according to the description 4 on their patient 52.

According to example embodiments, the reading step 26 entails a registration step 30 in the quality management system 18, which logs the read access by the doctor 28 to the knowledge capsule 24 in the access data 32. The fact that the user of the description 4 is the doctor 28 is stored there. The date and time of the read access are logged in the access data 32.

According to example embodiments, in an updating step 34 carried out by the quality management system 18, an assessment of the access data 32 is carried out since the access data 32 has been changed as a result of the access. This leads

to a modified representation 36 of the knowledge capsule 24. If it is requested by another user 38 in a new reading step 26, as indicated by the arrow 37, then the another user 38 is informed from the modified representation of the knowledge capsule 24 that the doctor 28 queried the knowledge 4 at the documented time, but there has not yet been any report about the use of the knowledge.

According to example embodiments, the user 38 may not find the description 4 of interest. In the new registration step 30 following the reading step 26, the access by the user 38 to the knowledge capsule 24 is added to the access data 32 by the quality management system 18. The user 38 decides not to use the description 4 and informs the quality management system 18 of this, whereupon the management system 18 compiles a corresponding entry in the quality data 20. The process connected with the user 38 is therefore concluded and ends here. In the meantime, the doctor 28 carries out the cancer therapy described in the description 4 on their patient 52 in a treatment step 28. This is in turn registered in the registration step 54 by the quality management system 18 and logged in the quality data 20.

According to example embodiments, two alternative method variants, indicated by the paths 56 and 58, are possible at this point in the example method according to Fig. 1. According to path 58, based on their subjective quality criteria 59, the doctor 28 evaluates how useful the knowledge in the form of the description 4 is or was for them with respect to the treatment of the patient 52. For this purpose, they describe and evaluate the disease profile of their patient 52 and the therapy carried out in the form of free text, which the quality management system 18 stores as a quality measure in a quality description 60 and adds to the quality data 20. The free text data are provided with context information, such as time of entry, address of the doctor 28, or the like.

The representation 62 of the knowledge capsule 24 thereupon changes so that another user, who later reads the description 4 out from the data memory 12, is also provided with the quality description 60 and thus obtains additional information about the new cancer therapy.

According to example embodiments, an automatic quality evaluation of the application of the description 4 by the doctor 28 takes place in the alternative path 56. Herein, the quality management system 18 reads out an electronic patient file 64 of the patient 52 and extracts the recovery time of the patient 52 therefrom. The length of the recovery of the patient 52, determined from the admission and discharge dates of the patient in the clinic of the doctor 28, is used as a quality criterion. From a comparison of the actual recovery time with the average recovery time of previous patients who were treated with conventional methods, for example, 12 months, and the recovery time measured at 9 months for the patient 52, a numerical quality measure 68 is calculated and added to the quality data 22. For example, this was a reduction by 3 months compared to the 4 months claimed by the research institution 2, which corresponded to a quality measure 68 of 75%. The quality measure 68 is added to the quality data 20. The description for determining the quality measure 68 (for example, calculation instruction, underlying data, boundary conditions) is stored together with this value in the quality data 20.

According to example embodiments, the representation 62 of a future read access to the knowledge capsule 24 is changed accordingly, as described above, so that a new user of the description 4 receives the knowledge capsule 24 together with the quality measure 68.

INDEPENDENT CLAIM 1

Independent claim 1 recites "storing knowledge data in a database of a memory." This reads on the non-limiting example embodiment disclosed, for instance, in paragraph [0073] of the original specification.

Independent claim 1 recites "correlating quality data with the knowledge data stored in the database." This reads on the non-limiting example embodiment disclosed, for instance, in paragraph [0074] of the original specification.

Independent claim 1 recites "a user at least one of storing the quality data in the database at least one of during and after access to the knowledge data." This reads on the non-limiting example embodiment disclosed, for instance, in paragraphs [0080-0083] of the original specification.

Independent claim 1 recites "storing result data from an application of the knowledge data in a result database and correlating quality data with the result data." This reads on the non-limiting example embodiment disclosed, for instance, in paragraph [0085] of the original specification.

Independent claim 1 recites "the application of the knowledge data being automatically generated and stored in the database." This reads on the non-limiting example embodiment disclosed, for instance, in paragraphs [0085-0086] of the original specification.

Independent claim 1 recites "the quality data automatically being provided to the user, upon the user accessing the knowledge data." This reads on the non-limiting example embodiment disclosed, for instance, in paragraph [0089] of the original specification.

Independent claim 1 recites "the quality data indicates a content quality of the knowledge data stored in the database." This reads on the non-limiting example

embodiment disclosed, for instance, in paragraph [0074] of the original specification.

INDEPENDENT CLAIM 29

Independent claim 29 recites "storing knowledge data in a database of a memory." This reads on the non-limiting example embodiment disclosed, for instance, in paragraph [0073] of the original specification.

Independent claim 29 recites "correlating quality data with the knowledge data stored in the database." This reads on the non-limiting example embodiment disclosed, for instance, in paragraph [0074] of the original specification.

Independent claim 29 recites "automatically providing, upon the user accessing the knowledge data, the quality data to the user." This reads on the non-limiting example embodiment disclosed, for instance, in paragraph [0087] of the original specification.

Independent claim 29 recites "the quality data indicates a content quality of the knowledge data stored in the database." This reads on the non-limiting example embodiment disclosed, for instance, in paragraph [0074] of the original specification.

VI. 37 C.F.R. § 41.37(c)(1)(vi) – GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Appellants seek the Board's review of the rejection of claims 1-19 and 22-30 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Application Publication No. 2004/0122719 ("Sabol").

VII. 37 C.F.R. § 41.37(c)(1)(vii) – ARGUMENT

A. Rejection of Claims 1-6, 9-19 and 22-30 under 35 U.S.C. § 102(e) is Erroneous

The Examiner takes the position that claims 1-19 and 22-30 are anticipated by U.S. Patent Application Publication No. 2004/0122719 ("Sabol"). Appellants respectfully disagree with the Examiner's position for the reasons expressed below.

Principles of Law

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."[1]

Cited Art Fails to Disclose All Claimed Limitations

Claim 1 recites *inter alia* "**correlating** quality data with the knowledge data stored in the database" where "the **quality data** indicates a ***content quality*** of the **knowledge data** stored in the database." Initially, Appellants note that Sabol relates to forecasting future resource needs use of medical modalities or other medical services based on existing data in an "integrated knowledge base 12."[2] Clinical and non-clinical data are stored in and accessed from an "integrated knowledge base 12" by physicians to fulfill their tasks, such as diagnosis and treatment of patients in Sabol.[3] This data in the integrated knowledge base 12

[1] *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).
[2] See Abstract of Sabol.
[3] See Figs. 1 and 7 of Sabol.

includes prescribable data sources such as "blood tests" or "urine tests," electrical data acquisition such as "ECG," and medical imaging techniques.[4]

The Examiner cites a part of Sabol, which further describes different types of data that may be included in the integrated knowledge base 12, and which is limited to patient record data.[5] The Examiner also cites another part of Sabol, which describes a method for how data from different sources, such as elements 98, 100, 102 in Fig. 7 of Sabol are processed on computing resources 20 via software 22 and made available by storage in the integrated knowledge base 12.[6]

Hence, **Sabol merely relates to storing medical data from various sources in to an integrated knowledge base**, which is then used to **predict future medical needs**, such as an amount of medical machines or medication. Therefore, even assuming *arguendo* that the Examiner relies on the entirety of the existing data stored in the integrated knowledge base 12 of Sabol to disclose the above limitation of claim 1 (which Appellants do not admit), such data could only be interpreted, at best, to disclose the "knowledge data" of amended claim 1. This is because, Sabol still fails to disclose any type of **secondary data** being stored in the integrated knowledge base 12 that is **generated from the use or application of the existing data** of the integrated knowledge base 12, and which indicates a **reliability or accuracy of the existing data** of the integrated knowledge base 12. As such, Sabol fails to disclose "**correlating** quality data with the knowledge data stored in the database" where "the **quality data** indicates a ***content quality*** of the **knowledge data** stored in the database," as recited in claim 1.

[4] See Para. [0001-0004, 0048-0049, 0066] of Sabol.
[5] See Para. [0061] of Sabol and Pg. 3 of the June 24, 2010 Office Action.
[6] See Para. [0079] of Sabol and Pg. 3 of the June 24, 2010 Office Action.

In response to the above arguments, the Examiner initially states that claim 1 recites "merely a database, whether is stores knowledge data or quality data."[7] Appellants find such a conclusion to be clearly erroneous as claim 1 is method which actively recites "storing" and "correlating" steps, with the "correlating" step including multiple sub-steps.[8] Therefore, the subject matter of claim 1 is clearly not merely directed to a database, but instead a method for generating quality data which indicates a content quality of the knowledge data.

Further, the Examiner argues that a "general detection string" of Sabol may disclose the above limitation of claim 1.[9] The "general detection string" is disclosed to "identify relevant data or relationships which were not specifically requested" and "correlate new data in accordance with relationships identified by the data processing system or integrated knowledge base."[10] The Examiner relies on the identified "relationships" of Sabol to disclose the "**correlating** quality data with the knowledge data" step of claim 1 and relies on the "relevant data" of Sabol to disclose the "quality data [which] indicates a ***content quality*** of the **knowledge data**."[11] However, the "relationships" in Sabol only relate to "grouping to identify risks, potential treatments, financial management options" or "new ways to diagnose or treat patients such as based upon recognizable trends or correlations, analysis of success or failure rates, statistical analyses of patient care results, and so forth."[12] **Therefore, the "relationships," "new data" and/or "relevant data" of Sabol only relate to comparing the data in the knowledge base to determine new trends within the data, and do *not* relate determining a *content quality or reliability* of the data itself.**

---

[7] See Examiner's response detailed on Pg. 13 of the June 24, 2010 Final Office Action.
[8] See claim 1 of Appellants' March 23, 2010 response.
[9] See Examiner's response detailed on Pg. 13 of the June 24, 2010 Final Office Action.
[10] See Para. [0318] of Sabol.
[11] See Examiner's response detailed on Pg. 13 of the June 24, 2010 Final Office Action.
[12] See Para. [0318-0319] of Sabol.

As a result, Sabol also fails to disclose that the "quality data" is stored "**during and after access** to the knowledge data", correlating quality data to "**an *application* of the knowledge data,**" and "the quality data ***automatically* being provided** to the user, **upon the user *accessing the knowledge data***," as recited in claim 1.

For at least the foregoing reasons, claim 1 is patentable over Sabol. Independent claim 29 is at least somewhat similar to claim 1 and therefore patentable for at least somewhat similar reasons. Dependent claims 2-19, 22-28 and 30 are at least patentable by virtue of their dependency on one of independent claims 1 and 29. Accordingly, Appellants respectfully request the Board to reverse the Examiner's rejection.

B. Rejection of Claims 7-8 under 35 U.S.C. § 102(e) is Erroneous

The Examiner takes the position that claims 7-8 are anticipated by U.S. Patent Application Publication No. 2004/0122719 ("Sabol"). Appellants respectfully disagree with the Examiner's position for the reasons expressed below.

Claim 7 recites a method of quality evaluation, wherein "quality data are determined from the result database according to quality criteria."

The Examiner alleges that FIG. 1 and Paragraphs [0061] and [0079] of Sabol anticipate the limitations of claim 7. Applicants disagree,

As mentioned above, Para. [0061] of Sabol is directed to data resources 38 including a range of information. This information may be included in a radiology department information system 44 or within a hospital information system 46. Additionally, patient history information may also be available.

However, none of this information is determined according to any quality criteria. Sabol fails to disclose or suggest any quality data and quality criteria. As a

result, Sabol fails to anticipate "quality data are determined from the result database according to quality criteria," as recited in claim 7. Further, dependent claim 7 is at least patentable by virtue of its dependency on independent claim 1. Accordingly, Appellants respectfully request the Board to reverse the Examiner's rejection.

Claim 8 recites a method of quality evaluation, wherein "quality data are determined from the result database according to the quality criteria with a time delay, and an access path to the result database is assigned to the quality criterion."

The Examiner alleges that FIG. 1 and Paragraphs [0061] and [0079] of Sabol anticipate the limitations of claim 8. Applicants disagree,

As mentioned above, Para. [0061] of Sabol is directed to data resources 38 including a range of information. This information may be included in a radiology department information system 44 or within a hospital information system 46. Additionally, patient history information may also be available.

However, none of this information is determined according to any quality criteria that include a time delay. Sabol discloses that a variety of data are collected, processed and analyzed at various points of time. However, this does not indicate the presence of any time delay in determining quality data. Further, as disclosed above, Sabol fails to teach or fairly suggest any quality data and quality criteria.

As a result, Sabol fails to anticipate "quality data are determined from the result database according to the quality criteria with a time delay, and an access path to the result database is assigned to the quality criterion," as recited in claim 8. Further, dependent claim 8 is at least patentable by virtue of its dependency on

independent claim 1. Accordingly, Appellants respectfully request the Board to reverse the Examiner's rejection.

CONCLUSION

Appellant respectfully requests the Board to reverse the Examiner's rejection of claims 1-19 and 22-30 and allow each of these claims.

If the USPTO believes that personal communication will further the prosecution of this application, the Office is invited to contact the undersigned at the telephone number below.

The Commissioner is authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

HARNESS, DICKEY, & PIERCE, P.L.C.

By: 

Donald J. Daley, Reg. No. 34,313
P.O. Box 8910
Reston, Virginia 20195
(703) 668-8000

DJD/AZP:cfc

VIII. 37 C.F.R. § 41.37(c)(1)(viii) – CLAIMS APPENDIX

1. (Previously Presented) A method for quality evaluation of electronically stored, knowledge data the method comprising:

storing knowledge data in a database of a memory; and

correlating quality data with the knowledge data stored in the database, where the correlating includes,

a user at least one of storing the quality data in the database at least one of during and after access to the knowledge data,

storing result data from an application of the knowledge data in a result database and correlating quality data with the result data,

the application of the knowledge data being automatically generated and stored in the database, and

the quality data automatically being provided to the user, upon the user accessing the knowledge data, wherein

the quality data indicates a content quality of the knowledge data stored in the database.

2. (Previously Presented) The method as claimed in claim 1, wherein

the user applies the knowledge data, and

quality data correlated with the results of the application are stored in the database.

3. (Previously Presented) The method as claimed in claim 1, wherein

quality criteria correlated with the knowledge data are stored in the database.

4. (Previously Presented) The method as claimed in claim 1, wherein

an identification of the user is assigned to the quality data and stored in the database.

5. (Previously Presented) The method as claimed in claim 1, wherein

the user determines quality data with a time delay after application of the knowledge data, and

the user is automatically requested to store the quality data in the database.

6. (Previously Presented) The method as claimed in claim 1, wherein

the result database is at least one of an electronic patient database and an electronic hospital information system, and

patient outcome data are stored as result data in the result database.

7. (Previously Presented) The method as claimed in claim 1, wherein

quality data are determined from the result database according to quality criteria, and

the quality data are stored in the database.

8. (Previously Presented) The method as claimed in claim 1, wherein

quality data are determined from the result database according to the quality criteria with a time delay, and

an access path to the result database is assigned to the quality criterion.

9. (Previously Presented) The method as claimed in claim 8, wherein

a result database denoted by the access path is automatically checked for the presence of the result data assigned to the quality criteria, and

when the result data are present, quality data are generated from them according to the quality criteria and stored in the database.

10. (Previously Presented) The method as claimed in claim 1, wherein

a quality measure is determined as quality data, and a determination instruction for the quality measure is stored in the database.

11. (Previously Presented) The method as claimed in claim 10, wherein

the determination instruction is at least one of a formula and an expert rule.

12. (Previously Presented) The method as claimed in claim 1, wherein

different users use the same knowledge data and quality data assigned to the users are determined therefrom, and

a ranking of the success rate of the users is calculated from the quality data.

13. (Previously Presented) The method as claimed in claim 1, wherein

comparable knowledge data are used and quality data assigned to the knowledge data are determined therefrom, and

a ranking of the quality of the knowledge data is calculated from the quality data.

14. (Previously Presented) The method as claimed in claim 1, wherein

knowledge data are released for use by the user only after the user has assigned their identification to the knowledge data or an access path for result data from the use of the knowledge data.

15. (Previously Presented) The method as claimed in claim 1, wherein

knowledge data are released for use by the user only after the user has paid a fee, and

the user receives a reimbursement of the fee after storing the quality data.

16. (Previously Presented) The method as claimed in claim 1, wherein

the use of the knowledge data is chargeable to the user, and

the quality data, but not the assigned knowledge data, is freely viewable by the user.

17. (Previously Presented) The method as claimed in claim 1, wherein

the date of the creation of the quality data is stored in the database together with the quality data.

18. (Previously Presented) The method as claimed in claim 1, wherein

at least one of medical treatment recommendations and advice is stored as knowledge data.

19. (Previously Presented) The method as claimed in claim 1, wherein

medical guidelines are stored as knowledge data.

20. - 21. (Cancelled)

22. (Previously Presented) The method as claimed in claim 2, wherein

quality criteria correlated with the knowledge data are stored in the database.

23. (Previously Presented) The method as claimed in claim 6, wherein

quality data are determined from the result database according to quality criteria, and

the quality data are stored in the database.

24. (Previously Presented) The method as claimed in claim 6, wherein

quality data are determined from the result database according to the quality criteria with a time delay, and

an access path to the result database is assigned to the quality criterion.

25. (Previously Presented) The method as claimed in claim 7, wherein

quality data are determined from the result database according to the quality criteria with a time delay, and

an access path to the result database is assigned to the quality criterion.

26. (Previously Presented) The method as claimed in claim 23, wherein

quality data are determined from the result database according to the quality criteria with a time delay, and

an access path to the result database is assigned to the quality criterion.

27. (Previously Presented) The method as claimed in claim 26, wherein

a result database denoted by the access path is automatically checked for the presence of the result data assigned to the quality criteria, and

when the result data are present, quality data are generated from them according to the quality criteria and stored in the database.

28. (Previously Presented) The method as claimed in claim 1, wherein the knowledge data is medical knowledge data.

29. (Previously Presented) A method for quality evaluation of electronically stored knowledge data the method comprising:

storing knowledge data in a database of a memory;

correlating quality data with the knowledge data stored in the database; and

automatically providing, upon the user accessing the knowledge data, the quality data to the user, wherein

the quality data indicates a content quality of the knowledge data stored in the database.

30. (Previously Presented) The method as claimed in claim 29, wherein the knowledge data is medical knowledge data.

IX. 37 C.F.R. § 41.37(c)(1)(ix) – EVIDENCE APPENDIX

None.

X. 37 C.F.R. § 41.37(c)(1)(x) – RELATED PROCEEDINGS APPENDIX

None.